K112988

NOV - 9 2011

510(k) SUMMARY

DATE: June 30, 2011

OWNER:
Northstar Healthcare Holdings
Hamilton House
10 Queen Street
Hamilton, Bermuda HM11

OFFICIAL CORRESPONDENT:
Michael Riordan
Northstar Healthcare Holdings Limited
3300 Cork Airport Business Park, Kinsale Road
Cork, Ireland
Telephone: 353 21 4548255
Fax: 353 21 4548294

DEVICE NAME:

Trade Name: Powder Free Latex Patient Exam Glove, Smooth and Textured Natural Color (Off White) with Protein Labeling Claim (50 µg/dm² or less of water soluble protein)

Common Name: Patient Examination Gloves

Classification: Patient Examination Gloves

Class: Class I

Product Code: LYY

PREDICATE DEVICE(S):

Predicate 510(k)	Device Name	Indication	Clearance Date	Company
K932521	Powder Free Latex Examination Gloves	The patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	13 Dec 1994	Top Glove SDN. BHD. Selangor Darul Ehsan, Malaysia

DEVICE DESCRIPTION: Powder Free Latex Patient Exam Glove, Smooth and Textured Natural Color (Off White) with Protein Labeling Claim (50 µg/dm² or less of water soluble protein)

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STATEMENT OF INTENDED USE:

The latex examination glove is a disposable device intended for medical purposes to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these gloves were tested for residual protein levels in accordance with ASTM D5712 Standard and contain 50µg/dm^2 or less of water soluble protein.

TECHNOLOGICAL CHARACTERISTICS:

The Powder Free Latex Patient Exam, Textured and Smooth with Protein Labeling Claim is substantially equivalent to the predicate device with regard to physical characteristics, design, product features, and intended use. Both gloves are made with latex using similar manufacturing processes.

ASSESSMENT OF NONCLINICAL DATA:

Characteristic	Standard	Device Performance
Dimension	ASTM Standard D3578	Meets
Physical Properties	ASTM Standard D3578	Meets
Freedom from Pinholes	21 CFR 800.20; ASTM D5151	Meets
Powder Residual	ASTM Standard D6124	Meets Results generated values below 2mg of residual powder
Biocompatibility	Primary Skin Irritation in rabbits (ISO 10993-10)	Gloves are non-irritating
	Dermal Sensitization in the guinea pig (ISO 10993-10)	Gloves do not display any potential for sensitization
Residual Protein Levels	ASTM Standard D5712	Meets

CONCLUSIONS:

The Powder Free Latex Patient Exam Gloves meet the requirements of established standards ASTM D3578-05, ASTM D6124-06, ASTM D5151-06, ASTM D5712-05e and ISO 10993-10.

Based on the comparison of intended use, design, materials and performance, the Powder Free Latex Patient Exam Gloves, Textured and Smooth, With Protein Labeling Claim are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Northstar Healthcare Holding Limited
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

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Re: K112988
Trade/Device Name: Powder Free Latex Patient Exam Glove, Smooth and Textured Natural Color (Off White) with Protein Labeling Claim (50ug/dm^2 or less of water soluble protein)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: October 26, 2011
Received: October 27, 2011

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112988

Device Name: Powder Free Latex Patient Exam Glove, Smooth and Textured Natural Color (Off White) with Protein Labeling Claim (50 µg/dm² or less of water soluble protein)

Indications for Use: The patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie Wilson
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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